510(k) Summary (Summary of Safety and Effectiveness)

JUN 2 6 2013

This summary of the 510(k) safety and effectiveness information is being submitted in the accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number

K131556

Applicant Name:

Dr. Abhijit Datta, Director of Technical Operations

Diazyme Laboratories

12889 Gregg Court

Poway, CA 92064

Abhijit.datta@diazyme.com

Date Summary was Prepared

June 10, 2013

Device Name:

Classification Name: Diazyme Lipoprotein (a) Calibrator Set and Diazyme Lipoprotein (a) Control Set

Trade Name: Diazyme Lp(a) Calibrator Set and Diazyme Lp(a) Control Set

Common Name: Diazyme Lp(a) Calibrator Set and Diazyme Lp(a) Control Set

Governing Regulation: 21 CFR 862.1150 (Calibrator, Primary); 21 CFR 862.1660 [Single (specificed) Analyte Controls (Assayed and Unassayed)]

Device Classification: Low Density Lipoprotein Immunological test system; Class II (Calibrator and Control

Classification Panel: Clinical Chemistry (75)

Product Code: JIT, JJX

Submission Type

Special 510k

Legally marketed device to which equivalency is claimed:

K082488, Diazyme Lp(a) calibrators and controls

Manufacturing Address

Diazyme Laboratories

12889 Gregg Court

Poway, CA 92064

Establishment Registration

2032900

Intended Use of Device:

The Diazyme Lipoprotein (a) Calibrator Set is intended for use in establishing the calibration curve for the Diazyme Lipoprotein (a) Assay reagents by turbidimetry. For *in vitro* diagnostic use only.

The Diazyme Lipoprotein (a) Control Set is intended for use in monitoring the quality control of results obtained with the Diazyme Lipoprotein (a) Assay reagents by turbidimetry. For *in vitro* diagnostic use only.

Description of Device:

The Diazyme Lipoprotein (a) Assay is based on a latex enhanced immunoturbidimetric assay. Lp(a) in the sample binds to specific anti-Lp(a) antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of Lp(a) in the sample.

Diazyme Lp(a) standard is intended for use in establishing the calibration curve for the Diazyme Lp(a) reagents by turbidimetry. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular diseases in specific populations, when used in conjunction with clinical evaluation.

Modification of Device:

The significant changes to the device are as follows:

- Change in state of material supplied from freeze-dried powder to liquid
- Change in packaging and labeling, specifically the change in catalog number
- No change to intended use claims

Based on the findings from verification and validation activities, the changes of the Diazyme Lp(a) Calibrator Set and Control Set (compared to predicate) do not alter the safety or effectiveness.

Similarities and Difference of Modified Device:

The table below compares the new device, Diazyme Lp(a) Calibrator Set and Control Set, with the predicate device, Diazyme Lp(a) Calibrators and Controls (K082488).

Attribute	Predicate Device **Diazyme Lipoprotein (a) Assay with Lyophilized Calibrators and Controls** (K082488)	New Device **Diazyme Lipoprotein (a) Calibrator Set and Control Set** (special 510k submission)
Intended Use	Diazyme Lp(a) standard is intended for use in establishing the calibration curve for the Diazyme Lp(a) reagents by turbidimetry. For *in vitro* diagnostic use only Diazyme Lp(a) Control is intended for use in monitoring the quality control of results obtained with the Diazyme Lp(a) reagents by turbidimetry.	Diazyme Lipoprotein (a) Calibrator Set is intended for use in establishing the calibration curve for the Diazyme Lipoprotein (a) Assay reagents by turbidimetry. For in vitro diagnostic use only. Diazyme Lipoprotein (a) Control Set is intended for use in monitoring the quality control of results obtained with the Diazyme Lipoprotein (a) Assay reagents by turbidimetry. For in vitro diagnostic use only.
Instrumentation	Hitachi 717	Olympus AU400
Lp(a) Calibrators	Lyophilized human serum and plasma	Liquid stable human serum and plasma
Calibrator Composition	Human serum, with active ingredient Lp(a)	Human serum, preservative, and active ingredient Lp(a)
Control Composition	Lyophilized human serum	Human serum, preservative, and active ingredient Lp(a)
Standardization	Using a single lot of predicate device reagents and calibrator, Diazyme Lp(a) master lot of calibrator materials were assigned values as follows. The calibrator materials were assayed as samples three times in triplicate on the Hitachi or Olympus Analyzer. For each calibrator level, mean values were calculated from the data points and assigned as the	Value Transfer from predicate device Diazyme Lp(a) Reagent and calibrator (K082488) to reference lot of liquid stable calibrators Using predicate device: Diazyme Lp(a) Latex Reagent and calibrator (K082488), Diazyme Lp(a) reference lot of liquid stable calibrator materials were assigned values

	calibrator value. For each new lot of calibrator materials produced, the master lot or reference lot calibrator is used in conjunction with the reference lot of Diazyme Lp(a) Assay reagents to test and verify calibrator value.	as follows: The calibrator materials were assayed as samples in triplicate on Beckman AU400 Analyzer. For each calibrator level, mean values were calculated and assigned as the initial calibrator value. Lp(a) Liquid Stable Calibrator Value Verification Reference lot of the Lp(a) liquid stable calibrator with the target values assigned are used to test library samples assigned with predicate device and trueness controls.
Calibrator Range	0-100 mg/dL	0-100 mg/dL
Analytical Sensitivity	5.44 mg/dL	5.44 mg/dL
LOB LOQ	LOB = 1.14 mg/dL LOQ = 5.44 mg/dL	LOB = 1.13 mg/dL LOQ = 5.44 mg/dL (Sensitivity checked to confirm previously approved data)
Dynamic Range	Up to 100 mg/dL Lp(a)	Up to 100 mg/dL Lp(a)

Verification/Validation of Modification:

The nonclinical performance of the Diazyme Lp(a) Calibrator Set and Control Set was demonstrated through the following studies:

- 20-Day Precision
- Limits of Blank/Detection/Quantitation (LOB/LOD/LOQ)
- Linearity
- Accuracy by Method Comparison
- Accuracy by Matrix Comparison
- Interference
- Accelerated Calibrator Stability
- Real Time Calibrator Stability
- Accelerated Control Stability
- Real Time Control Stability
- Open and Closed Vial Calibrator Stability
- Value Assignment and Traceability

Conclusion:

Current Diazyme Lp(a) Assay reagent and calibrators (k082488) were selected for comparing serum Lp(a) levels to the results generated by the modified device Diazyme Lp(a) Calibrator Set and current Diazyme Lp(a) Assay reagent. The accuracy between the results obtained by Diazyme Lp(a) Assay Kit (k082488) and proposed calibrators and controls (Diazyme Lp(a) Calibrator Set and Control Set) unequivocally demonstrates excellent correlation. As a result, the Lp(a) Calibrator Set and Control Set use for measurement of Lp(a) in patient serum samples is substantially equivalent to legally marketed devices. The differences in the calibrator components (lyophilized versus liquid stable) should not affect the safety and effectiveness of the Diazyme Lp(a) Assay reagents.

In summary, the dissimilar composition features of the Diazyme Lp(a) Calibrator Set and control Set (compared to predicate) do not affect the safety or effectiveness of the Diazyme Lp(a) Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2013

Diazyme Laboratories
C/O Dr. Abhijit Datta
12889 Gregg Court
POWAY CA 92064

Re: K131556
Trade/Device Name: Diazyme Lipoprotein (a) Calibrator Set and Diazyme Lipoprotein (a) Control Set
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT, JJX
Dated: May 28, 2013
Received: May 29, 2013

Dear Dr. Datta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number : k131556

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Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k131556